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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,323	12/20/2004	Masazumi Nishikawa	263192US0PCT	3573

22850 7590 11/20/2006

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EXAMINER
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VENKAT, JYOTHSNA A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/517,323

Applicant(s)

NISHIKAWA ET AL.

Examiner

JYOTHSNA A. VENKAT Ph. D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/25/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner of this application is changed from Desta Yebassa to Jyothsna Venkat.

Receipt is acknowledged of IDS and amendment filed on 9/25/06 and 7/19/06. Claims 11-17 have been added as per applicant's amendment dated 7/19/06.

Rejection of claims 5-10 and 11-17 under 35 U. S. C. 112 first paragraph is maintained with respect to "preventing skin damage".

### ***Response to Arguments***

Applicant's arguments filed 7/19/06 have been fully considered but they are not persuasive.

Applicants state that:

"Applicants note the Office's position that the working examples described in the present specification are directed "to treating skin damage and not to preventing skin damage." (Present Office Action at page 4, lines 18-19). However, Applicants respectfully submit that the Office has misunderstood and misinterpreted the examples. In particular, Applicants note that the working examples described in the present specification are directed to preventing skin damage, not to treating it. Specifically, in the present specification, Examples 1 and 2 clearly demonstrate that when a composition containing diacylglycerol ether derived from a shark liver oil had been orally administered to HR-1 hairless mice and guinea pigs for two weeks, and then UVB was irradiated, the formation of wrinkled skin and sagging skin or the formation of skin cancer was successfully prevented. The specification, as originally filed, also clearly recites in no uncertain terms that the claimed composition is useful in prevention of the skin damage. Accordingly, the Office's attention is directed to following quotations from the present specification: Based on the

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test results of Example 1, it was inferred that the feed containing the diacylglyceryl ether-containing composition mixed therein suppressed significantly ( $p < 0.05$ ) wrinkle formation due to UVB irradiation and thus was useful in prevention of the formation of wrinkled skin and sagging skin or the formation of skin cancer. In addition, it was clear that the feed containing the diacylglyceryl ether-containing composition mixed therein suppressed the onset of cancer. (Page 10, last paragraph of the Example 1). Based on the test results of experiment 2, it was inferred that because the diacylglyceryl ether-containing composition showed a tendency to suppress UV erythema formation, the composition is useful in alleviation of skin redness (sunburn) or melanism (suntan). (Page 12, last paragraph of the Example 2). Thus, Examples 1 and 2 are clearly directed to preventing skin damage, and the present specification well provides enablement for a method of preventing skin damage. “

In response to the above argument, it is the position of the examiner that etiology for wrinkle is different from skin cancer. Wrinkles are related to aging process and skin cancer is not related to aging process. Additionally there are two main types of skin cancer. First type is malignant melanoma and second type is non-melanoma skin cancer. The non-melanoma skin cancer can be basal cell carcinoma or squamous cell carcinoma. Examples did not show that all these types of skin cancer were prevented. Additionally examples in 1-2 did not show that preventing of skin damage was achieved using the compounds of formula I. What is R1-R3 in examples 1-2? There was no data that formation of pigmented spots and freckles was prevented using compounds of formula I. Thus the specification does not provide evidence that the compositions as disclosed prevented all types of skin cancer, prevented wrinkle formation, sagging of skin, age spots and freckles by oral administration taking any dosage and using any

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compound belonging to formula I (emphasis added). Prevention entails the complete and absolute inhibition of the onset of the disease or symptom and any manifestation of the disease or symptom entirely, and this had not been demonstrated by the applicants. Therefore, 112 rejection is deemed proper.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A. VENKAT Ph. D whose telephone number is 571-272-0607. The examiner can normally be reached on Monday-Friday, 10:30-7:30:1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JYOTHSNA A VENKAT Ph. D  
Primary Examiner  
Art Unit 1615

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